

In re: Odidi et al.
Serial No. 09/845,497
Docket No. 9577-25

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Amendments to the Specification:

Please replace paragraph [38] with the following amended paragraph:

[38] The present invention is an extended release pharmaceutical active formulation that comprises pharmaceutical active that can be in the form of a capsule, tablet, pellet or bead which is encased with an encasement coat in the form of one or more layers of a pH sensitive polymeric film that is soluble above a pH of about 5.0. The capsule, tablet, pellet or bead of pharmaceutical active comprises about 5-95% by weight pharmaceutical active, optionally about 0-60% by weight pharmaceutical compression aid, and optionally about 0-50% by weight of a pharmaceutical extrusion aid. The pharmaceutical compression aid may be selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar. ~~The pharmaceutical extrusion aid may be microcrystalline cellulose and other extrusion aids as is understood by one of skill in the art.~~ The capsule, tablet, pellet or bead of pharmaceutical active may optionally comprise excipients, lubricants, binders or glidants.

Please replace paragraph [40] with the following amended paragraph:

[40] The present invention further provides a method for making pharmaceutical active tablets preferably by dry granulation or direct compression and encasement of the tablet in at least one layer of pH sensitive polymeric film(s). Dry granulation can be accomplished by slugging. The tablet may also be made by first processing pharmaceuticals alone or with suitable excipients via wet granulation or fluid bed granulation or spray drying before tableting. To the tablet is optionally added 0-60 % by weight of one or more pharmaceutical compression aids such as lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate, and compressible sugar which have high compactibility, good flowability and blending properties and good stability. To the tablet is also optionally added 0-50% by weight extrusion aids ~~such as microcrystalline cellulose~~. The tablet may also contain lubricants, binders or glidants.